MEMO

To: Manufacturers of Medical Devices and Biologics

From: Kate Whelley McCabe, AAG; Wendy Morgan, AAG, Chief of Public Protection Division

Office of Vermont Attorney General

Date: February 21, 2014

Re: Offer of Limited Penalty for Failure to Report

This memorandum serves as official notice that the Vermont Attorney General is offering to accept a payment to the State in the amount of \$10,000 per reporting period to settle failures to report under the Prescribed Products Gift Ban and Disclosure Law for prior reporting years. This offer applies only to medical device and biologic manufacturers whose obligation to comply with the Prescribed Products Gift Ban and Disclosure Law began on or after July 1, 2009, but who failed to report their activities for any of the following reporting periods: FY10 (7/1/09-6/30/10), FY11 (7/1/10-6/30/11), 2011 (7/1/11-12/31/11), 2012 (1/1/2012-12/31/2012), or who anticipate failure to report for 2013 (1/1/2013-12/31/2013).

This offer is for amnesty from additional financial penalties the Attorney General is authorized to seek under the Law for failures to report, and from the back-payment of registration fees. **It does not apply to other violations of the law, such as gift ban violations.** Moreover, in order to obtain amnesty, the manufacturer must execute an Assurance of Discontinuance to secure its future compliance with the law.

This offer will remain open until **May 1, 2014**. In order to take advantage of the offer, manufacturers must email prescribedproducts@atg.state.vt.us on or before May 1st with the following information:

- manufacturer name
- reporting period(s) for which the manufacturer failed to report
- name, physical address, email address and phone number of person with whom the Office should communicate about the unreported activity. While the Office does not anticipate seeking full disclosure for unreported activity, the Office does anticipate requiring disclosure— at a later date— of some aggregate information related to the activity, as well as information as to whether the manufacturer also gave gifts in violation of the Gift Ban.

Please refer to the Office's website for more information about the Prescribed Products Gift Ban and Disclosure Law. You may email prescribed-products@atg.state.vt.us with questions about this offer. Please be aware that it may take the Office up to a week to respond to your email.